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PATENT *Image*  
858610-2003.2

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s) : De-Chu TANG, et al.  
Serial No. : 10/052,323  
For : IMMUNIZATION OF ANIMALS BY TOPICAL  
APPLICATION OF A SALMONELLA-BASED VECTOR  
Filed : January 18, 2002  
Examiner : TBA  
Art Unit : 1632

745 Fifth Avenue  
New York, NY 10151

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William S. Frommer, Reg. No. 25,506

(Name of Applicant, Assignee or Registered Representative)

  
Signature

October 29, 2003

Date of Signature

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

The Examiner's attention is invited to the enclosed documents set forth on the accompanying form PTO-1449, enclosed in duplicate. These publications were cited in the International Search Report of related International Application No. PCT/US03/01599. Copies of the cited documents are enclosed.


This Information Disclosure Statement is not a representation that the documents cited herein are considered most pertinent, or that a search has been undertaken, or that any of the cited documents are indeed prior art. The Examiner is invited to undertake an independent search.

This Information Disclosure Statement is being filed before receipt of the first Office Action on the merits (a restriction requirement was mailed July 16, 2003). However, the Commissioner is hereby authorized to charge any such fee, or credit any overpayment to Deposit Account 50-0320.

Applicants request that the Examiner consider and make of record the documents cited herein and that a copy of the Form PTO-1449, initialed by the Examiner be returned to the undersigned.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP  
Attorneys for Applicants

By:   
William S. Frommer  
Reg. No. 25,506  
(212) 588-0800



Sheet 1 of 1

Based on Form PTO-148  
(3/90)

ATTY. DOCKET NO.

858610-2003.2

SERIAL NO.

10/052,323

LIST OF REFERENCES CITED BY APPLICANT  
(Use several sheets if necessary)

APPLICANT

Tang, et al.

FILING DATE

January 18, 2002

GROUP

1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
9W	AA	6,339,068 B1	01/15/02	Krieg, et al.	—	—	
	AB	5,679,647	10/21/97	Carson, et al.	—	—	
	AC	6,348,450 B1	02/19/02	Tang, et al.	—	—	
	AD	2003/0045492 A1	03/06/03	Tang, et al.	—	—	
	AE						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AF							
	AG							
	AH							
	AI							
	AJ							
	AK							
	AL							
	AM							
	AN							

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

7W	A0		Babiuk, S., et al., "Topical delivery of plasmid DNA using biphasic lipid vesicles (Biphaxix)," J. Pharm, Pharmacol., Dec. 2002, Vol. 54, No. 12, pages 1609-1614.
1	AP		Van Oirschot, J.T., "Present and future of veterinary viral vaccinology: A review," Vet. Quart., July 2001, Vol. 23, No. 3, pp. 100-108.
1	AQ		Barnfield, C., et al., "The cellular basis of immune induction at mucosal surfaces by DNA vaccination," Dev. Biol. 2000, Vol. 104, pp 159-64.

EXAMINER

DATE CONSIDERED

11/30/04

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PATENT  
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11/7/02

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Art Unit : To Be Determined

Examiner : To Be Determined

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*Charles Jackson*  
(Typed or printed name of person mailing paper or fee)

*Charles Jackson*  
(Signature of person mailing paper or fee)

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

The Examiner's attention is respectfully directed to the documents which are set forth on the accompanying form PTO-1449. Since these documents were forwarded to, or cited by, the Examiner in related applications, U.S. Serial No. 09/402,527, filed October 5, 1999, and U.S. Serial No. 09/563,826, filed May 3, 2000 (now U.S. Patent 6,348,450) and a copy of each of these documents should be in the parent application files, no additional copy is being forwarded with this Information Disclosure Statement.

As this Information Disclosure Statement is being filed before the mailing of the first Office Action on the merits, it is believed that no fee is required for entry of this paper. However, the Commissioner is hereby authorized to charge any such fee, or credit any overpayment to Deposit Account 50-0230.

The filing of this Information Disclosure Statement is not an admission that the documents identified herein constitute prior art to the present application.

Applicants respectfully request that the Examiner considers and make of record the documents cited herewith and that a copy of Form PTO-1449 be initialed by the Examiner and returned to the undersigned.

Respectfully submitted,

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FROMMER LAWRENCE & HAUG LLP  
Attorney for Applicants

By: 

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
72	AA	5,616,326	04/01/97	Spibey			
	AB	4,797,368	1/10/89	Carter et al.			
	AC	4,775,630	10/4/88	Tibbetts et al			
	AD	4,806,350	2/21/89	Gerber			
	AE	4,863,970	9/5/89	Patel et al			
	AF	4,944,942	7/31/90	Brown et al			
	AG	4,929,442	5/29/90	Powell			
	AH	4,623,541	11/18/86	Elliot et al			
	AI	4,674,490	6/23/87	Frankel et al			
	AJ	4,594,244	6/10/86	Lehner et al			
	AK	4,405,616	9/20/83	Rajadhyaksha			
	AL	5,679,647	10/21/97	Carson et al.			

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

72	AM	Stephenson, J. "Defective adenoviruses as novel vaccines for the Flaviviridae." Abstract only, Clin Diag. Virol. 15 July 1998, vol. 10, pgs 187-194.
	AN	Saikh et al. "Are DNA-based vaccines useful for protection against secreted bacterial toxins? Tetanus toxin test case." Abstract only, Vaccine. May 1998, Vol. 16, pgs 1029-1038.
	AO	Antohi et al. "The reactivity pattern of hemagglutinin-specific clonotypes from mice immunized as neonates or adults with naked DNA." Abstract only. International Immunology. May 1998, Vol. 10, pgs 663-668, abstract only.
	AP	Fan et al. "Immunization via Hair Follicles by Topical Application of Naked DNA to Normal Skin." Nature Biotechnology. September 1999, vol. 17, pages 870-872, see entire article.
	AQ	Neimiec et al. "Perifollicular Transgenic Expression of Human Interleukin-1 receptor Antagonist Protein following Topical Application of Novel Liposome-Plasmid Formulations in vivo." J. of Pharmaceutical Sciences. June 1997, vol. 86, no. 6, pgs 701-708.
	AR	Scaria et al. "Complementation of a human adenovirus early region 4 deletion mutant in 293 cells using adenovirus-polylysine-DNA complexes. Abstract only", Gene Ther. June 1995, Vol 2, No. 4, pgs 295-298.
	AS	English Abstract for International Patent No. WO 94/10323
	AT	English Abstract for Canadian Patent No. 2,234,201

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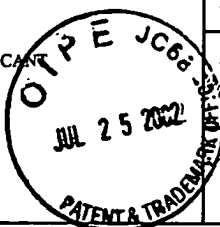
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
90	AU	4,557,934	12/10/85	Cooper			
	AV	5,703,055	12/30/97	Felgner et al			
	AW	5,693,622	12/2/97	Wolff et al			
	AX	5,707,812	1/13/98	Horn et al			
	AY	5,817,637	10/6/98	Weiner et al.			
	AZ	5,593,972	1/14/97	Weiner et al.			
	BA	5,804,566	9/8/98	Garson et al.			
	BB	5,505,945	4/9/96	Gristina et al.			
	BC	5,580,859	12/3/96	Felgner et al			
	BD	5,589,466	12/31/96	Felgner et al.			
	BE	5,795,972	8/18/98	Kmiec			
	BF	5,731,181	3/24/98	Kmiec			
	BG	5,830,177	11/3/98	Li et al.			
	BH	5,753,263	5/19/98	Lishko et al			
	BI	5,872,005	2/16/99	Wang et al.			
	BJ	5,206,163	4/27/93	Renard et al.			
	BK	5,700,680	12/23/97	Newton et al.			
	BL	5,707,618	1/13/98	Armentano et al.			
	BM	5,792,462	8/11/98	Johnston et al			
	BN	5,872,005	2/16/99	Wang et al.			
	BO	5,998,382	12/7/99	Furth et al.			
	BP	5,756,086	5/26/98	McClelland et al.			
	BQ	5,851,806	12/22/98	Kovesdi et al.			
	BR	5,700,910	12/23/97	Metzger et al.			
	BS	5,846,559	12/8/98	Hopp			
	BT	5,885,808	3/23/99	Spooner et al.			

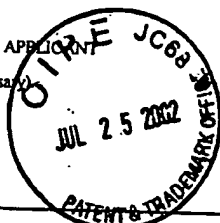
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
dw	BU	5,874,279	2/23/99	Cochran et al.			
	BV	5,718,902	2/17/98	Yilma et al.			
	BW	5,849,719	12/15/98	Carson et al.			
	BX	5,872,154	2/16/99	Wilson et al.			
	BY	5,872,005	2/16/99	Wang et al.			
	BZ	5,736,387	4/7/98	Paul et al.			
	CA	5,494,807	2/27/96	Paoletti et al.			
	CB	5,882,877	3/16/99	Gregory et al.			
	CC	5,762,939	6/9/98	Smith et al.			
	CD	5,547,932	8/20/96	Curiel et al.			
	CE	5,658,785	8/19/97	Johnson			
	CF	5,665,362	9/9/97	Inglis et al.			
	CG	5,698,443	12/16/97	Henderson et al.			
	CH	5,763,270	6/9/98	Eastman et al.			
	CI	5,770,442	6/23/98	Wickham et al.			
	CJ	5,786,211	7/28/98	Johnson			
	CK	5,824,538	10/20/98	Branstrom et al.			
	CL	5,830,463	11/3/98	Duke et al.			
	CM	5,766,599	6/16/98	Paoletti et al.			
	CN	5,780,448	7/14/98	Davis			
	CO	5,662,098	9/2/97	Yoshida			
	CP	5,648,096	7/15/97	Gander et al.			
	CQ	5,645,834	7/8/97	Cockrum			
	CR	5,616,329	4/1/97	Newman et al.			
	CS	5,530,102	6/25/96	Gristina et al.			
	CT	5,505,945	4/9/96	Gristina et al.			

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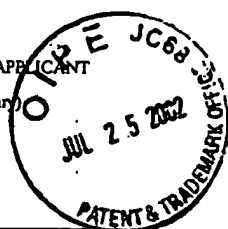
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SW	CU	5,891,690	4/6/99	Massie			
	CV	5,882,877	3/16/99	Gregory et al.			
	CW	5,731,172	3/24/98	Saito et al.			
	CX	5,698,202	12/16/97	Ertl et al.			
	CY	5,585,362	12/17/96	Wilson et al.			
	CZ	5,707,618	1/13/98	Armentano et al.			
	DA	5,880,102	3/9/99	George et al.			
	DB	5,703,055	12/30/97	Felgner et al.			
	DC	5,700,470	12/23/97	Saito et al.			
	DD	5,753,500	5/19/98	Shenk et al.			
	DE	5,635,380	6/3/97	Naftilan et al.			
	DF	5,580,859	12/3/96	Felgner et al.			
	DG	5,830,877	11/3/98	Carson et al.			
	DH	5,589,466	12/31/96	Felgner et al.			
	DI	5,679,647	10/21/97	Carson et al.			
	DJ	5,591,439	1/7/97	Plotkin et al.			
	DK	5,846,559	12/8/98	Hopp			
	DL	5,834,256	11/10/98	Finer et al.			
	DM	5,753,263	5/19/98	Lishko et al.			
	DN	5,866,383	2/2/99	Moss et al.			
	DO	5,830,177	11/3/98	Li et al.			
	DP	5,679,647	10/21/97	Carson et al.			
	DQ	5,023,252	6/11/91	Hseih			
	DR	5,139,941	8/18/92	Muzyczka et al.			
	DS	5,552,309	9/3/96	March			
	DT	5,635,380	6/3/97	Naftilan et al.			

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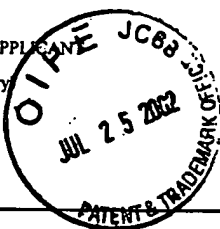
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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
sw	EI	3,837,340	9/24/74	Counter			
	EJ	3,962,424	6/8/76	Zygraich et al.			
	EK	3,950,512	4/13/76	Emery et al.			
	EL	3,608,030	9/21/71	Tint			
	EM	3,906,092	9/16/75	Hillerman et al.			
	EN	4,738,846	4/19/88	Rose et al			
	EO	4,089,801	5/16/78	Schneider			
	EP	4,217,344	8/12/80	Vanlerberghe et al			
	EQ	4,235,871	11/25/80	Papahadjopoulos et al			
	ER	4,241,046	12/23/80	Papahadjopoulos et al.			
	ES	4,394,448	7/19/83	Szoka, Jr. et al			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
sw	ET	WO 99/15683	4/1/99	WIPO				
	EU	WO 99/08713	2/25/99	WIPO				
	EV	WO 90/11092	10/4/90	WIPO				
	EW	WO 92/11028	7/9/92	WIPO				
	EX	WO 98/03641	1/29/98	WIPO				

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sw	EY	Alexander et al., "Liposome-mediated Gene Transfer and Expression via the skin," Human Molecular Genetics, 1995, Vol. 4, no. 12, pp. 2279-2285
	EZ	Auturm et al., (2000) "Adhesive force of a single gecko foot-hair." Nature, 405 (6787): 681-5
	FA	Brandsma et al., (1991) "Use of a rapid, efficient inoculation method to induce papillomas by cottontail rabbit papillomavirus DNA shows that the E7 gene is required." PNAS USA 88: 4816-4820
	FB	Choate and Khavari, (1997) "Direct Cutaneous Gene Delivery in a Human Genetic Skin Disease" Human Gene Therapy 8: 1659-1665
	FC	Ciernik et al. (1996) "Puncture-Mediated Gene Transfer to the Skin," Human Gene Therapy, vol. 7, 893-899
	FD	Donnelly et al. (1997) "DNA Vaccines", Life Sciences, vol 60, no. 3, 163-172

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
70	FE	0 638 316 A1	2/15/95	EUROPE			
	FF	298142 A1	1/11/89	EUROPE			
	FG	406778 A1	1/9/91	EUROPE			
	FH	286798 A2	10/19/88	EUROPE			
	FI	0 773 295 A2	5/14/97	EUROPE			
	FJ	WO 00/66179	11/9/00	WIPO			
	FK	WO 95/05853	3/2/95	WIPO			
	FL	WO 99/15683	4/1/99	WIPO			

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

70	FM	Guo, Z. et al., "Efficient and sustained transgene expression in mature rat oligodendrocytes in primary culture." J. Neurosci. Res., vol. 43, no. 1, 32-41, January 1, 1996 (Abstract)
	FN	Khavari, P., "Therapeutic gene delivery to the skin." (1997) Molecular Medicine Today, vol. 3, 533-538.
	FO	Panchagnula et al., "Animal models for transdermal drug delivery." (1997) Meth. Find. Exp. Clin. Pharmacol., 19(5): 335-341
	FP	Todryk et al., (1996) "Induction of Immune responses to functional determinants of a cell surface streptococcal antigen," Immunology, vol. 87, 55-63.
	FQ	Tsukui et al., (1996) "Transgenesis by adenovirus-mediated gene transfer into mouse zona-free eggs", Nature Biotechnology, vol. 14, 982-985.
	FR	Lu et al., "Topical Applications of Viral Vectors for Epidermal Gene Transfer", The Journal of Investigative Dermatology, vol. 108, no. 5, May 1997
	FS	Huyghe et al., "Purification of a Type 5 Recombinant Adenovirus Encoding Human p53 by Column Chromatography", Human Gene Therapy, vol. 6, pp. 1403-1416, November 1995
	FT	Tang et al., "Butyrate-inducible and tumor-restricted gene expression by adenovirus vectors", Cancer Gene Therapy, vol. 1, no. 1, pp. 15-20, 1994
	FU	Remus et al. "Insertion of Foreign DNA into an Established Mammalian Genome Can Alter the Methylation of Cellular DNA Sequences", Journal of Virology, vol. 73, no. 2, pp. 1010-1022, February 1999
	FV	Brown et al., "Adenoviral Vectors Given Intravenously to Immunocompromised Mice Yield Stable Transduction of the Colonic Epithelium", Gastroenterology, vol. 112, pp. 1586-1594, 1997
	FW	Wang et al., "Correction of a Deletion Mutant by Gene Targeting with an Adenovirus Vector", Molecular and Cellular Biology, vol. 13, no. 2, pp. 918-927, February 1993
	FX	Tsukui et al., "Transgenesis by adenovirus-mediated gene transfer into mouse zona-free eggs", Nature Biotechnology, vol. 14, pp. 982-985, August 1996
	FY	Niemic et al., "DNA Perifollicular Transgenic Expression of Human Interleukin-1 Receptor Antagonist Protein following Topical Application of Novel Liposome-Plasmid DNA Formulations In Vivo", Journal of Pharmaceutical Sciences, vol. 86, no. 6, June 1997 pp. 701-708, June 1997
	FZ	Ciernik et al., "Puncture-Mediated Gene Transfer to the Skin", Human Gene Therapy, vol. 7, pp. 893-899, May 20, 1996


EXAMINER

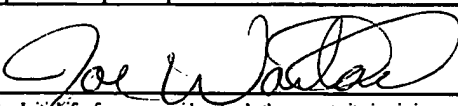
Joe W. Tadae

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		FILING DATE <b>January 18, 2002</b>		GROUP <b>To Be Determined</b>	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)					
70	GA		Condon et al., "DNA-based immunization by in vivo transfection of dendritic cells", Nature Medicine, vol. 2, no. 10, pp. 1122-1126, October 1996		
	GB		Yang, N.S. et al., "Gene gun and other non-viral approaches for cancer gene therapy" Nat. Med., vol. 1, no. 5, 481-481, May 1995 (Abstract)		
	GC		Raz et al., "Intradermal gene immunization: The possible role of DNA uptake in the induction of cellular immunity to viruses", Proc. Natl. Acad. Sci. USA, vol. 91, pp. 9519-9523, September 1994		
	GD		Greenhalgh et al., "Epidermis: An Attractive Target Tissue for Gene Therapy", Gene Therapy, vol. 103, no. 5, pp. 63S-69S, November 1994		
	GE		Yokoyama et al., "DNA immunization: Effects of vehicle and route of administration on the induction of protective antiviral immunity", FEMS Immunology and Medical Microbiology, vol. 14, pp. 221-230, 1996		
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LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT <b>Tang et al.</b>			
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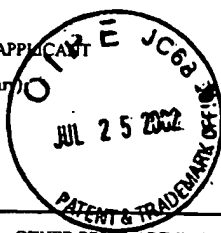
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